

Rec'd PCT/PTO 24 AUG 2004

10/505569  
REC'D 03 JUN 2004

## PATENT COOPERATION TREATY

PCT

WIPO PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P1009PC00</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416																									
International application No. <b>PCT/SE 2003/000329</b>	International filing date (day/month/year) <b>27.02.2003</b>	Priority date (day/month/year) <b>27.02.2002</b>																								
International Patent Classification (IPC) or national classification and IPC <b>A61K 38/40, A61P 9/00</b>																										
Applicant <b>Norrby, Klas</b>																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </tbody> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																								
<input type="checkbox"/>	Box No. II	Priority																								
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																								
<input type="checkbox"/>	Box No. IV	Lack of unity of invention																								
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																								
<input type="checkbox"/>	Box No. VI	Certain documents cited																								
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																								
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																								

Date of submission of the demand <b>23.09.2003</b>	Date of completion of this report <b>17.05.2004</b>
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer <b>Micael Owald/Els</b> Telephone No. +46 8 782 25 00

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/000329

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, Nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_  
 the claims, Nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superceded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/000329

## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application
- claims Nos. 1-16 (partially) and 17-32

because:

- the said international application, or the said claims Nos. 17-32  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-16 (part.)  
are so unclear that no meaningful opinion could be formed (*specify*):

Claims 1, 3-10 and 13-16 relate to a large number of possible vascular diseases and states of tissue hypoperfusion with hypoxic or ischemic consequences for which support within the meaning of Article 5 and 6 PCT is lacking. Consequently, the search has been carried out for those parts of the claims

.../...

- the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

- no international search report has been established for said claims Nos. 1-16 (partially)

- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form  has not been furnished

does not comply with the standard

the computer readable form  has not been furnished

does not comply with the standard

- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

- See Supplemental Box for further details.

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

PCT/SE 2003/000329

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box III.2

which appear to be supported and disclosed, namely those disclosed in claims 2, 11 and 12.

Claims 1-4, 11-16 relate in respect of the wording "...peptides derivable from human lactoferrin and/or natural metabolites of human lactoferrin and/or functionally equivalent analogues of human apo-lactoferrin..." to a large number of possible compounds for which support within the meaning of Article 5 and 6 PCT is lacking. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely to human lactoferrin, apolactoferrin and the variants disclosed in the dependent claims.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/000329

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	<u>2-10, 12, 15-16</u>	YES
	Claims	<u>1, 11, 13-14</u>	NO
Inventive step (IS)	Claims	<u>2, 12</u>	YES
	Claims	<u>1, 3-11, 13-16</u>	NO
Industrial applicability (IA)	Claims	<u>1-16</u>	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

Documents cited in this opinion:

D1: Patent Abstracts of Japan, JP7278011 A (Morinaga Milk Ind Co Ltd).

D2: WO 0001730 A1.

D3: STN International, File CAPLUS, AN=1997:501617, DN=127:210350, JP 09194388.

D4: Dialog Information Services, File 155, Medline, Medline Acc.No: 98321919.

D1 describes a therapeutic agent for angina pectoris. The active substance is obtained by hydrolyzing lactoferrin of mammals (e.g. from human) or apolactoferrin. Claims 1, 11, 13-14 therefore lack novelty.

It is further considered that it is obvious for a person skilled in the art to use human (apo)lactoferrin or derivatives thereof in different preparations since no unexpected technical effect has been shown. Further since no unexpected technical effect has been shown for the use of the derivatives described in D2. Claims 1, 3-11, 13-16 therefore lack inventive step.

D3 describes angiogenic disease treating agents containing lactoferrins or their hydrolyzates. The lactoferrin is obtained from milk and is administered as tablet, ointment or spray. Claims 1, 13-14 therefore lack novelty.

.../...

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

PCT/SE 2003/000329

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

It is further unclear if the peptide derivatives according to claims 4-10 have novelty over what is disclosed in D3 (see pag. 7-9).

D4 describes that human lactoferrin reduce cell damage after hypoxia. D4 describes a study on a cell line and does not refer to therapeutics. However it is considered obvious for a person skilled in the art to formulate a therapeutic composition containing human lactoferrin or derivatives thereof to treat conditions associated with hypoxia. Claims 1, 3-10, 13-16 therefore lack inventive step.